ABBOTT

Corporate Regulatory Affairs

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June 15, 1999

Food and Drug Administration
Dockets Management Branch (HFA -305)
5630 Fishers Lane
Rockville, MD 20852

RE: Exports: Notification and Recordkeeping Requirements
[Docket No. 98N-0583]

Dear Sirs or Madams:

Abbott Laboratories submits the following remarks in response to the Agency's request for comments on the above-named subject and docket. Abbott is an integrated worldwide manufacturer of healthcare products employing more than 56,000 people and serving customers in more than 130 countries.

I. SPECIFIC COMMENTS

In general, the proposed rule is overreaching and contrary to Congressional intent. The FDA Export Reform and Enhancement Act of 1996 (Export Act) was passed to eliminate impediments to U.S. exports of medical products. During the legislative process, Congressman Upton, a major force behind the Export Act, was concerned that future agency action would erode the purpose of the Export Act. To this end Congressman Upton stated, "[i]t is very clear that the majority of the Members believe that the export provisions are a trade issue first and foremost." (104 Cong. Rec. H4094, April 25, 1996, statement of Rep. Upton). He also stated, "[t]he FD&C Act, under this amendment, is altered to make it easier to export drugs and devices..." (xx Cong. Rec. H4094, April 25, 1996, statement of Rep. Upton). Congressman Upton concluded his remarks by stating that there should be "almost no restrictions on the export of medical products to nations which allow them for sale." (104 Cong. Rec. H4095, April 25, 1996, statement of Rep. Upton).

With this context in mind, it becomes apparent that the extensive record keeping requirements imposed on U.S. medical product manufacturers by this proposed rule are in conflict with Congressional intent to eliminate impediments to U.S. exports of medical products. Furthermore, it is difficult to find support in the law for many of the proposed record keeping requirements. The following specific items are illustrative:

1. Sections 801 and 802 of the Food, Drug & Cosmetic Act (FD&C Act) provide two different methods of exporting a drug or device. As noted in the introduction to the proposed rule, FDA is relying on the record keeping provision provided under section 802(g). The record keeping provisions of 802(g) apply to drugs or devices exported in accordance with section 802(a). FDA, however, in its proposed rule, expands the record keeping provisions by applying it to products intended for export under the alternative method of export provided by 801(e). This application is contrary to the provisions provided by the law and should be curtailed. The record keeping provision of 802(g) does not apply to the export of product under 801(e).

2. Proposed sections 1.101(b) and 1.01(e)(2) require maintaining records for at least five years from the date of exportation. In the case of multiple shipments of the same type of product, the date of last exportation is appropriate. However, the rule should clarify that its intent is the date of last exportation. The five-year record retention period is excessive. A two-year record retention period is more appropriate and agrees with FDA's device Quality System record retention provision (see 21 CFR section 820.180(b)).

3. Proposed section 1.01(b)(1) requires records describing the product specifications requested by the foreign purchaser. The rule provides examples of specifications, such as dosage strength, dosage form, purity, quality, operating parameters, composition, and sterility. Many products, in vitro diagnostic devices for example, are not manufactured to unique purchaser specifications. Rather, such products are offered for sale to the general laboratory/scientific community. In these cases, it is the manufacturers' package inserts which describes the product specifications. The rule should be clarified to include the manufacturers' package inserts as appropriate documentation to satisfy proposed section 1.01(b)(1).

4. Proposed section 1.01(b)(2), requiring a letter from the importing government agency stating the imported product does not conflict with the laws of the importing country, exceeds the provisions of the law. The law states a product "shall not be deemed to be adulterated or misbranded...if it is not in

conflict with the laws of the country to which it is intended for export." To require U.S. manufacturers to obtain a written letter from such countries is clearly beyond the FD&C Act. This imposes an unduly burdensome and unnecessary requirement on the foreign government agencies. It likewise imposes a heavy trade impediment on U.S. medical product manufacturers, since export will be dependent upon the agencies' resource allocations. For these reasons, this provision should be stricken.

5. The proposed rules regarding partially processed biologics present a few issues. First, partially processed biologics are exported pursuant to section 351(h) of the Public Health Service Act (PHS Act). This section of the PHS Act requires meeting the provisions of 801(e)(1) of the FD&C Act. The record keeping provisions under proposed rule 1.01(b) are derived from the record keeping requirements under 802(g). The record keeping provision of 802(g) does not apply to the export of product under 801(e). Applying the record keeping provisions of section 802(g) to section 801(e) is contrary to the law and should be deleted. Second, proposed rule 1.01(c), requiring demonstration that a partially processed biologic is not in a form applicable to the prevention, treatment, or cure of disease or injuries of man, should be stricken. A partially processed biologic is just that, a partially processed biologic. Creating records to demonstrate a partially processed biologic is not something else is impractical.

6. Proposed rule 1.01(d)(1), requiring U.S. manufacturers to notify FDA when exporting in anticipation of marketing authorization, and once marketing authorization is received, is problematic. As stated by the law, manufacturers are to notify FDA upon receipt of marketing authorization. To require duplicate notification is inefficient for both FDA and manufacturers. Requiring duplicate notification, in contrast to the law, will double the record keeping responsibilities of manufacturers and FDA. Proposed rule 1.01(d)(1) should exempt exports under sections 802(d) as was done for exports under section 802(c).

7. Proposed rule 1.01(d)(1)(iv), which would require "notification...[of the] country that is to receive the exported article," exceeds the requirement of the law. It should be written to state, "the country that has provided a valid marketing authorization by the appropriate authority," in accordance with 802(b)(1)(A) of the FD&C Act. Proposed rule 1.01(e)(1), which contains a similar provision, should also be clarified to reflect the law as stated in section 802(b)(1)(A) of the FD&C Act. This application of the law is supported by Congressman Upton's statement, referring to the Export Act, "[it] allows

pharmaceuticals and medical devices not approved in the United States to be exported to any country in the world if the product complies with the laws of that country and has valid marketing authorization in one of the following countries: Australia; Canada; Israel; Japan; New Zealand; Switzerland; South Africa; or the European Union or a country in the European Economic Area." (104 Cong. Rec. April 30, 1996, statement of Rep. Upton). By relying on the record keeping provision to require U.S. manufacturers to notify FDA of every country receiving the product, the rule would exceed Congressional intent.

8. Clarification of proposed rule 1.01(e)(1)(iv) is required. Often products are exported to a distribution center outside of the U.S. In requiring the consignee's name and address, the rule should clarify that it is the name and the address of the distribution center that is required.

9. The proposed rule underestimates the financial impact of the rule. This statement is supported by the following data from one firm:

Notification Type	Average* Files/Year	Average Records/Year	Manhours/ Export Notification	Manhours/ Preparation Export File
801(e)	5	5	N/A	24-32
802(e)	10	7	0.75	16
Partially Processed Biologic	18	5	N/A	16

*averages based on 1997-1999 data

II. GENERAL OBSERVATIONS

Consistency with other Publications. The FDA has asked for comments on other publications on this same subject. See Docket Nos. 98D-0307 and 98N-0496. A benefit to all parties would be the comparison of the relevant proposed rules and the guidances.

III. CLOSING COMMENTS

The final rule should be implemented through a "phasing in" of the regulation to minimize the impact on commerce. The final promulgation and implementation of the proposed rule should be undertaken in conjunction with an industry-wide educational effort for the following reasons:

A. General educational purposes. Due to the cost and broad scope of this proposal, any seminars on the final rule will help everyone concerned. These seminars should be carried out in conjunction with the US Customs Service which is a party to these new regulations. The proposed seminars could be carried out with the support of FDLI, AFDO, HIMA or other scientifically-oriented trade associations. The Agency should also consider a telecast similar in format to the FDLI's show on latex which was held on May 5, 1998. The agenda for this broadcast was developed through a consensus-based approach and drew upon the collective expertise of the FDA, industry, and particularly the other Federal Agencies which may be involved.

B. Publicity. The impact of this proposed rule will affect regulatory practices and expectations of manufacturers. By carrying out these seminars, the Agency can publicize and prepare all concerned for the new requirements.

C. Clarity. Finally, public seminars will serve to clarify regulatory expectations and interpretations.

Yours truly,

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Philip L. Chao, FDA, Office of Policy (HFA-23)
Kimberly A. Cressotti, FDA, Div. of Case Management (HFM-610)
[Docket 98D-0307]
[Docket 987N-0496]

98D-0307

C12

CROSS FILE SHEET

FILE NO: 98D-0307/C12

SEE FILE NO: 98N-0583/C11

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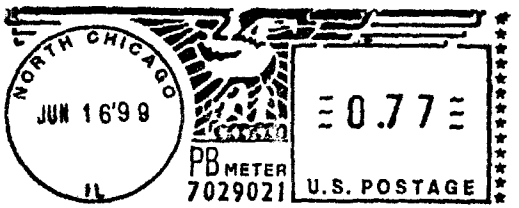

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